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EXAMINER				
DINH, BACH T				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/560,015

**Applicant(s)**

KOBAYASHI, TAIZO

**Examiner**

BACH T. DINH

**Art Unit**

1795

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-20 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
- Paper No(s)/Mail Date 12/08/2005
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Summary***

1. This is the initial Office Action based on the 10/560,015 filed on 12/08/2005.
2. Claims 1-20 are current pending and have been fully considered.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 112***

4. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites "the insulating film includes an island portion which is in a form of an island and which includes the control edge", which implies that the island portion is part of the insulating film. However, the originally filed specification discloses "the stopper portion 16B may be in the form of a rectangular island which is separate from the insulating film" (page 14 lines 13 and page 15 lines 6-10), which implies that the island is not a part of the insulating film. Therefore, the recited limitation is indefinite for the apparatus as claimed conflicts with the support provided by the originally filed specification.

Claims 11-12 are rejected as dependents of claim 10.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

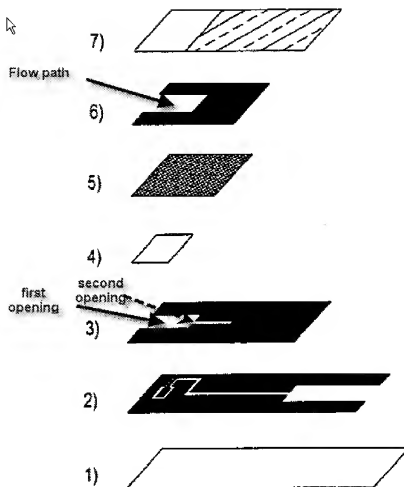
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Stiene et al. (WO 02/32559) with equivalent English translation provided by Stiene et al. (US 6,719,923).

Addressing claim 1, Stiene discloses an analytical tool (figure 1 is inserted below) with opening in insulating film 3, the tool comprising a substrate 1, a flow path for moving a sample along the substrate (figure 1), a reagent portion 4 provided in the flow path, and an insulating film 3 covering the substrate and including a first opening for defining a region for forming the reagent portion (figure 1);

Wherein the insulating film further includes at least one additional opening (second opening) positioned downstream from the first opening in a movement direction in which the sample moves (see figure 1).

Figure 1



Addressing claim 2, Stiene discloses the flow path is configured to move the sample by capillary force (figure 1, incoming sample would inherently move through the flow channel via a capillary force).

Addressing claim 3, current claimed apparatus is drawn to an analytical tool; therefore, the nature of the sample does not add any structural limitations to the apparatus.

However, if the limitation of current claim is given due consideration, Stiene discloses the sample is blood (1:5-13).

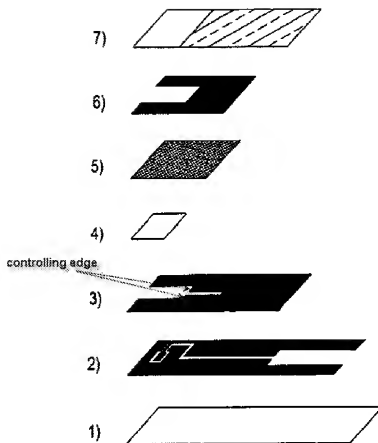
Addressing claim 4, Stiene discloses a first and second electrodes provided at the substrate (first and second electrodes of the electrode arrangement 2 in figure 1);

Wherein the insulating film 3 covers the first and second electrodes, with part of the first and second electrodes exposed (parts of the electrodes are exposed at the first opening in figure 1).

Addressing claim 5, Stiene discloses the at least one additional opening (second opening) is connected to the first opening (figure 1 above); and

Wherein the insulating film 3 includes a control edge (controlling edge as indicated below) defining a downstream edge of the region for forming the reagent portion in the movement direction.

Figure 1



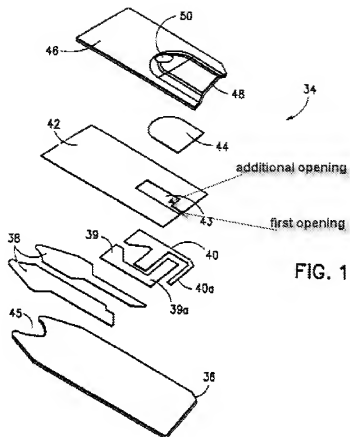
Addressing claims 6-7, Stiene discloses the additional opening (second opening) is connected to the first opening at a portion of the control edge (figure 1 above) adjoining in a direction which is perpendicular to the movement direction (the control edge as indicated above extends perpendicularly to the movement direction; therefore, the first opening and second opening are adjoined by the control edge in a perpendicular direction to the movement direction.

7. Claims 1-4 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Musho et al. (US 2001/0042683).

Addressing claim 1, Musho discloses an analytical tool (figures 1-2) with opening in insulating film, a flow path for moving a sample along the substrate (the capillary flow space formed in the insulating film 42), the tool comprising a substrate 36, a reagent portion provided in the flow path (reagent layer 44 provided in the capillary flow space on the electrodes, [0013]) and an insulating film 42 [0013] covering the substrate and including a first opening (see attached picture below) for defining a region for forming the reagent portion;

Wherein the insulating film further includes at least one additional opening (see attached picture below) positioned downstream from the first opening in a movement direction in which the sample moves.





Wherein the insulating film 42 covers the first and second electrodes, with part of the first and the second electrodes exposed (figures 1-2).

Addressing claim 17, Musho discloses at least part of the at least one additional opening is offset relative to the first opening in a direction which is perpendicular to the movement direction (figure 1, part of the additional opening as indicated above is offset relative to the first opening as required by current claim).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

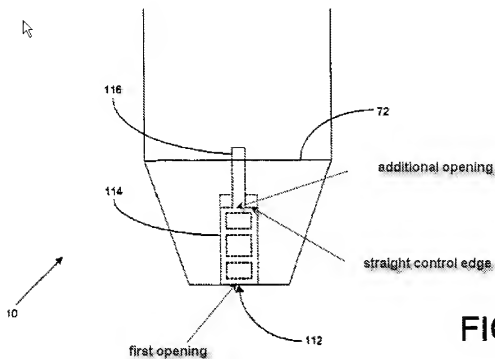
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Neel et al. (US 6,946,299).

Addressing claim 1, Neel discloses an analytical tool (figures 3-5) with opening in insulating film, the tool comprising a substrate (substrate 12), a flow path for moving a sample along the substrate (flow path 88), a reagent portion 90 provided in the flow path, and an insulating film (insulating film 64, 6:41-42) covering the substrate and including a first opening (first opening as indicated below for figure 5) for defining a region for forming the reagent portion;

Wherein the insulating film 64 further includes at least one additional opening (additional opening as indicated below) positioned downstream from the first opening in a movement direction in which the sample moves.



**FIG. 5**

Addressing claim 2, Neel disclose the flow path is configured to move the sample by capillary force (7:8-12).

Addressing claim 3, current claimed apparatus is drawn to an analytical tool; therefore, the nature of the sample does not add any structural limitations to the apparatus.

However, if the limitation of current claim is given due consideration, Neel discloses the sample is blood (see Abstract).

Addressing claim 4, Neel discloses a first 22 and a second 24 electrodes provided at the substrate;

Wherein the insulating film 64 covers the first and the second electrodes, with part of the first and second electrodes exposed (figure 2).

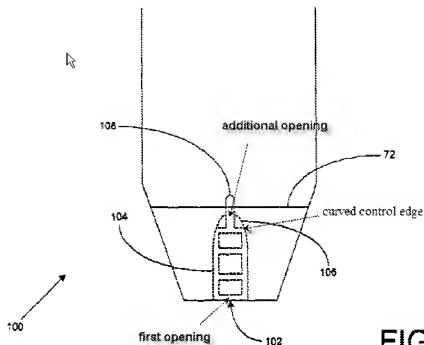
Addressing claim 5, Neel discloses the at least one additional opening is connected to the first opening (see inserted figure 5 above); and

Wherein the insulating film 64 includes a control edge (see the control edge as indicated in figure 5 above, 8:62-9:10) defining a downstream edge of the region for forming the reagent portion in the movement direction.

Addressing claim 6, Neel discloses the at least one additional opening is connected to the first opening at a portion of the control edge adjoining in a direction which is perpendicular to the movement direction (see inserted figure 5 above).

Addressing claim 7, Neel discloses the control is a straight line (see inserted figure 5 above) extending in a direction which is perpendicular to the movement direction.

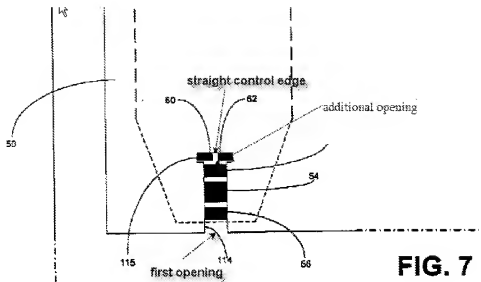
Addressing claim 9, Neel discloses the control is in a form of a curved line dented toward a downstream side in the movement direction (see inserted figure 4 with the curved control edge as indicated below).



10. Claims 1-5, 7 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Neel et al. (US 6,743,635).

Addressing claim 1, Neel discloses an analytical tool (figures 1-3) with opening in insulating film, the tool comprising a substrate 12, a flow path 88 for moving a sample along the substrate, a reagent portion 99 provided in the flow path, and an insulating film 54 covering the substrate and including a first opening (first opening as indicated in the inserted figure below) for defining a region for forming the reagent portion;

Wherein the insulating film 54 further includes at least one additional opening positioned (additional opening as indicated in the inserted figure below) downstream from the first opening in a movement direction in which the sample moves.



Addressing claim 2, Neel discloses the flow path 88 is configured to move the sample by capillary force (7:1-6).

Addressing claim 3, current claimed apparatus is drawn to an analytical tool; therefore, the nature of the sample does not add any structural limitations to the apparatus. However, if the limitation of current claim is given due consideration, Neel discloses the sample is blood (see Abstract).

Addressing claim 4, Neel discloses a first 22 and a second 24 electrodes provided at the substrate (figure 3);

Wherein the insulating film 54 covers the first and the second electrodes, with part of the first and second electrodes exposed (figure 7).

Addressing claim 5, Neel discloses the first opening and the at least one additional opening is connected to the first opening (see inserted figure 7 above); and

Wherein the insulating film includes a control edge (straight control edge as indicated in the inserted figure above) defining a downstream edge of the region for forming the reagent portion (the straight control edge is located downstream from the reagent portion) in the movement direction.

Addressing claim 7, Neel discloses the control edge is in a form of a straight line extending in a direction which is perpendicular to the movement direction (see inserted figure 7 above).

Addressing claim 17, Neel discloses at least part of the at least one additional opening as indicated above is offset relative to the first opening in a direction which is perpendicular to the movement direction (figure 7, part of the additional opening is not in the same line as the first opening; therefore, part of the additional opening is offset relative to the first opening).

Addressing claim 18, Neel discloses the flow path is formed by stacking a cover 72 to the substrate 12 via a spacer 64 (6:45-49);

Wherein the spacer includes a pair of surfaces (figure 8, side walls of the spacer 64) defining a dimension of the flow path 88 in a direction which is perpendicular to the movement direction and facing each other while being spaced from each other in the

perpendicular direction (figure 8, the side walls of the spacer 64 are the claimed surfaces); and

Wherein the spacing between the paired facing surfaces is larger than a dimension of the first opening in the perpendicular direction (figure 8, the spacing between the side walls of the spacer is larger than the width of first opening defined by the insulating film 54).

Addressing claim 19, Neel discloses the flow path 88 is configured to move the sample by capillary force (7:1-6).

### *Claim Rejections - 35 USC § 103*

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.



13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,946,299).

Addressing claim 8, in figure 5, Neel is silent regarding a dimension of the control edge in the perpendicular direction is set to 60 to 95 % of a dimension of the first opening in the perpendicular direction.

Neel discloses the vented slot is configured to allow the sample to flow through the sample chamber more smoothly and uniformly (8:57-61). Furthermore, one recognizes that the width of the straight control edge on either side of vented slot in figure 5 determines the width of the opening or claimed additional opening of the vented slot. At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the analytical tool of Neel by experimenting with the width of the control edge because the width of the control edge correlates to the width of the opening of the vented slot, which control the flow of the sample through the sample chamber (8:57-61, figure 5). Therefore, one would have arrived at the claimed dimension of the control edge in the perpendicular direction is set to 60 to 95% of a dimension of the first opening in the perpendicular direction when performing routine experiments to optimize the smoothness and uniformity of the flow of the sample through the sample chamber.

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635) in view of Nankai et al. (US 5,120,420).

Addressing claim 20, Neel discloses break 84 is used for venting to the sample chamber 84 to facilitate the movement of the sample in the chamber (6:60-7:12).

Neel is silent regarding the cover 72 includes a discharge port for discharging as from within the flow path.

Nankai discloses an analytical tool; wherein, the cover 9 includes a discharge port 11 for discharging gas from within the flow path (5:19-29) and a downstream end of the opening of introducing port 10 is positioned upstream from an upstream end of the discharge port 11 in the movement direction.

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the analytical tool of Neel with the discharge port in the cover 72 instead of the break 84 in the spacer as disclosed by Nankai because having the discharge port in the cover would still allow one to discharge gas in the sample chamber and facilitate the capillary movement of the sample through the chamber (Nankai, 5:6-29). Furthermore, one skilled in the art would have expected success when modifying the analytical tool of Neel with the discharge port in the cover as disclosed by Nankai because the cover including the discharge port, separate or in combination, would not have performed a materially different function.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

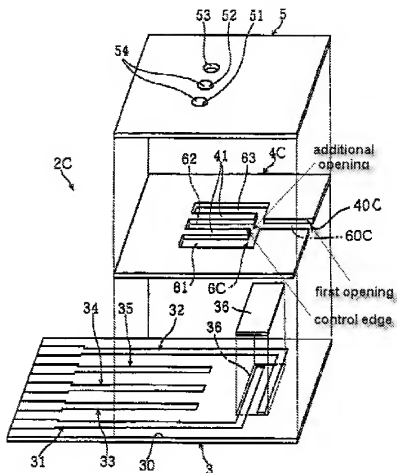
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 1-7, 13-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato (WO03012421) with equivalent English translation Sato (US 7,047,795) in view of Chang et al. (US 6,787,013).

Addressing claim 1, Sato discloses an analytical tool (figure 10), the tool comprising a substrate (3), a flow path (60c) for moving a sample along the substrate, a reagent portion (36) provided in the flow path (9:36-43), and a spacer (4) covering the substrate and including a first opening (first opening as indicated in the inserted figure 10 below) for defining a region for forming the reagent portion;

Wherein the spacer further includes at least one additional opening (see inserted figure below) positioned downstream from the first opening in a movement direction in which the sample moves.

FIG.10



Furthermore, one skilled in the art would recognize that the spacer 4 must be made from an insulating material in order to electrically insulate the electrodes deposited on the substrate. However, Sato lacks explicit disclosure regarding the material of the spacer 4. Chang discloses an analytical tool like that of Sato; wherein, the spacer 9 is made of insulating material (2:43-48).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the analytical tool of Sato with the insulating spacer material of Chang

because the insulating material would provide electrical insulation between the electrodes. Moreover, one skilled in the art would recognize that the spacer must be made from insulating material; therefore, such modification is well within the technical grasp of one with ordinary skill in the art. The insulating spacer is the claimed insulating film of current claim.

Addressing claim 2, Sato discloses the flow is configured to move the sample by capillary force (2:44-46).

Addressing claim 3, current claimed apparatus is drawn to an analytical tool; therefore, the nature of the sample does not add any structural limitations to the apparatus. However, if the limitation of current claim is given due consideration, Sato discloses the sample is blood (2:39-40).

Addressing claim 4, Sato discloses a first and second electrodes (electrodes 31 and 32) provided at the substrate 3;

Wherein the insulating film covers the first and second electrode, with part of the first and second electrodes exposed (figure 10).

Addressing claim 5, Sato discloses the at least one additional opening is connected to the first opening (see inserted figure 10 above); and

Wherein the insulating film includes a control edge defining a downstream edge of the region for forming the reagent portion in the movement direction (see inserted figure 10 above with the indicated control edge).

Addressing claim 6, Sato discloses the at least one additional opening is connected to the first opening at a portion of the control edge adjoining in a direction which is perpendicular to the movement direction (see inserted figure 10 above, the control edge extends in a perpendicular direction to the movement direction).

Addressing claim 7, Sato discloses the control edge is in a form of a straight line extending in a direction which is perpendicular to the movement direction (see inserted figure 10 above).

Addressing claim 13, Sato discloses the insulating spacer film includes a peninsula portion which is in a form of peninsula and which includes the control edge (projection 41 is the peninsular that includes the control edge, see figure 10).

Addressing claim 14, Sato discloses the at least one additional opening includes a pair of additional openings arranged to adjoin the peninsula portion in a width direction (in figure 10, either the pair of openings 61 and 62 adjoining the projection 41 or either the pair of openings 62 and 63 adjoining the projection 41 is the claimed pair of additional openings).

Addressing claim 15, Sato discloses the paired openings has a constant width (figure 10).

Addressing claim 17, Sato discloses at least part of the at least one additional opening (opening 61 of the additional opening) is offset relative to the first opening in a direction which is perpendicular to the movement direction (see figure 10).

*Allowable Subject Matter*

18. Claims 10-12, pending the 35 USC 112, 2<sup>nd</sup> paragraph rejection above, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
19. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 10-12, the prior art is silent regarding an analytical tool that include an island portion with a control edge for the express purpose of preventing the reagent solution to form the reagent portion from spreading more than necessary in the movement direction as disclosed by current application (page 10 lines 5-26, page 14 lines 9-27 of the originally filed specification). Moreover, the prior art is silent regarding any island portions included in an analytical tool that resemble the claimed island portion of current application. Therefore, the prior art does not disclose nor render obvious all the cumulative limitations of claims 1, 4, 5 and 10 with particular attention to the island

portion for preventing the reagent solution from spreading more than necessary in the movement direction of the sample as disclosed by current application.

Pending the 35 USC 112, 2<sup>nd</sup> paragraph rejection above, claims 11-12 are objected to as dependents of claim 10.

With respect to claim 16, Sato is silent regarding each of the paired openings includes a narrow portion positioned relatively upstream in the movement direction and a wide portion positioned downstream from the narrow portion; in fact, Sato only discloses each of the paired openings includes a channel with uniform width. Furthermore, one skilled in the art would not have found it obvious to modify the channel of each of the paired openings to include a narrow portion upstream from the wide portion because such modification would restrict the sample flowing into the respective channel of each of the paired openings. Therefore, the prior art does not disclose nor render obvious all the cumulative limitations of claims 1, 4-5, 13-14 and 16 with particular attention to the limitation regarding each of the paired openings includes a narrow portion positioned relatively upstream in the movement direction and a wide portion positioned downstream from the narrow portion as required by current application.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BACH T. DINH whose telephone number is (571)270-5118. The examiner can normally be reached on Monday-Friday EST 7:00 A.M.-3:30 P.M.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/  
Supervisory Patent Examiner, Art Unit 1753

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06/03/09